



Application No. 10/517,686  
Filed: August 8, 2005  
Attorney Docket No. 0470-045923

Customer No. 28289

1615  
Ifw

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/517,686  
Applicants : **Evert Johannes BUNSCHOTEN et al.**  
Received : December 10, 2004  
Title : **METHOD OF TREATING OR PREVENTING  
IMMUNE MEDIATED DISORDERS AND  
PHARMACEUTICAL FORMULATION FOR  
USE THEREIN**  
International Application : No. PCT/NL03/00422  
International Filing Date : 11 June 2003

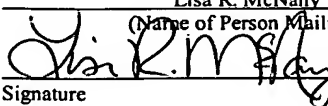
**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to the requirements of 37 CFR §§ 1.56, 1.97, and 1.98, the Applicants hereby submit this Information Disclosure Statement together with a completed Form PTO/SB/08A and one copy of the references listed thereon.

This application is the United States national phase of PCT Application No. PCT/NL03/00422. The International Search Report dated September 24, 2003 for the underlying PCT Application identified the references listed on Form PTO/SB/08A. A copy of the International Search Report is enclosed for the Examiner's convenience.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on August 8, 2005	
Lisa R. McNary (Name of Person Mailing Paper)	
	August 8, 2005
Signature	Date

Application No. 10/517,686  
Paper Dated: August 8, 2005  
Attorney Docket No. 0470-045923

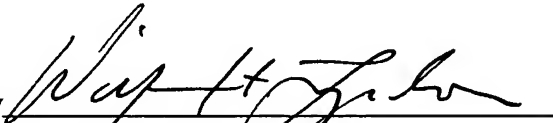


Customer No. 28289

Pursuant to 37 C.F.R. § 1.97(b)3, no fee is believed to be due for the submission of this Information Disclosure Statement, as it is being submitted before the mailing date of a first Office Action on the merits. Nevertheless, the Commissioner for Patents is hereby authorized to charge any fees which may be required to Deposit Account No. 23-0650. One (1) original and two (2) copies of this Information Disclosure Statement are enclosed.

Respectfully submitted,

THE WEBB LAW FIRM

By 

William H. Logsdon  
Registration No. 22,132  
Attorney for Applicants  
700 Koppers Building  
436 Seventh Avenue  
Pittsburgh, PA 15219-1818  
Telephone: (412) 471-8815  
Facsimile: (412) 471-4094  
E-mail: webblaw@webblaw.com



Please design (+) inside this box → ☐

PTO/SB/08A (08-00)

Approved for use through 10/31/2001. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

### Complete if Known

Application Number	10/517,686
Filing Date	December 10, 2004
First Named Inventor	Evert Johannes BUNSCHOTEN et al.
Group Art Unit	
Examiner Name	
Attorney Docket Number	0470-045923

Sheet 1 of 3

### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup>			

### FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
	1	WO	95/17895		Ehrlich et al.	07-06-1995		
	2	DE	199 17 930 A1		Schering AG	10-19-2000		
	3	WO	00/73416		University of Cincinnati	12-07-2000		
	4	WO	01/85154 A2		Oregon Health Sciences University et al.	11-15-2001		

### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cite and/or country where published.
	5	ALLEN ET AL., An Ovarian Hormone: Preliminary Report on Its Localization, Extraction and Partial Purification, and Action in Test Animals, JAMA, September 8, 1923, Vol. 81, pp. 819-821.
	6	ALLEN ET AL., The Induction of a Sexually Mature Condition in Immature Females by Injection of the Ovarian Follicular Hormone, Am. J. Physiol., 1924, Vol. 69, pp. 577-588.
	7	FISHMAN, Fate of 15a-Hydroxyestriol- <sup>3</sup> H in Adult Man, J. Clin. Endocrinol. Metab., 1970, Vol. 31, pp. 436-438.
	8	JONES ET AL., The Effects of Various Steroids on the Vaginal Histology in the Rat, Fertility and Sterility, April 1973, Vol. 24, No. 4, pp. 284-291.

Examiner  
Signature

Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

{W020225.1}



Please place a plus sign (+) inside this box → ☒

PTO/SB/08A (08-00)  
Approved for use through 10/31/2001. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/517,686
				Filing Date	December 10, 2004
				First Named Inventor	Evert Johannes BUNSCHOTEN et al.
				Group Art Unit	
				Examiner Name	
Sheet	2	of	3	Attorney Docket Number	0470-045923

<b>OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS</b>		
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cite and/or country where published.
	9	TULCHINSKY ET AL., Plasma Esterol as an Index of Fetal Well-Being, J. Clin. Endocrinol. Metab., 1975, Vol. 40. pp. 560-567.
	10	TSENG ET AL., Competition of Esterol and Ethynylestradiol with Estradiol for Nuclear Binding in Human Endometrium, Journal of Steroid Biochemistry, 1976, Vol. 7, pp. 817-822.
	11	MARTUCCI ET AL., Uterine Estrogen Receptor Binding of Cathecholestrogens and of Esterol (1,2,5(10)-Estratriene-3,15a,16a,17 $\beta$ -Tetrol), Steroids, March 1976, Vol. 27, No. 3, pp. 325-333.
	12	MARTUCCI ET AL., Direction of Estradiol Metabolism as a Control of its Hormonal Action - Uterotrophic Activity of Estradiol Metabolites, Endocrin., 1977, Vol. 101, pp. 1709-1715.
	13	TSENG ET AL., Heterogeneity of Saturable Estradiol Binding Sites in Nuclei of Human Endometrium Esterol Studies, Steroid Biochem., 1978, Vol. 9, pp. 1145-1148.
	14	HOLINKA ET AL., "In Vivo Effects of Esterol on the Immature Rat Uterus", Biology of Reproduction, Society for the Reproduction Society for the Study of Reproduction, Champaign, IL, US, March 1979 (1979-03), Vol.20, No. 2, pp. 242-246.
	15	HOLINKA, ET AL., "Comparison of Effects of Esterol and Tamoxifen with Those of Estriol and Estradiol on the Immature Rat Uterus", Biology of Reproduction, Society for the Reproduction Society for the Study of Reproduction, Champaign, IL, US, 1980, Vol. 22, No. 4, pp. 913-926.
	16	JOZAN ET AL., Different Effects of Oestradiol, Oestriol, Oestrol and of Oestrone on Human Breast Cancer Cells (MCF-7) in Long Term Tissue Culture, Acta Endocrinologica, 1981, Vol. 98, pp. 73-80.
	17	HAMMOND ET AL., A Versatile Method for the Determination of Serum Cortisol Binding Globulin and Sex Hormone Binding Globulin Binding Capacities, 1983, Vol. 132, pp. 101-110.
	18	LEVINE ET AL., Uterine Vascular Effects of Esterol in Nonpregnant Ewes, Am. J. Obstet. Gynecol., 1984, Vol. 148, No. 73. Pp. 735-738.

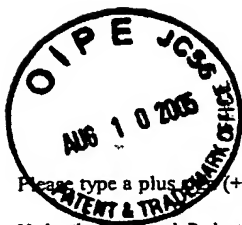
Examiner Signature	Date Considered
-----------------------	--------------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O.Box 1450, Alexandria, VA 22313-1450.

{W0202225.1}



Please type a plus (+) inside this box → ☐

PTO/SB/08A (08-00)  
Approved for use through 10/31/2001. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/517,686
				Filing Date	December 10, 2004
				First Named Inventor	Evert Johannes BUNSCHOTEN et al.
				Group Art Unit	
Sheet	3	of	3	Examiner Name	
				Attorney Docket Number	0470-045923

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cite and/or country where published.
	19	JANSSON ET AL., "Estrogen Induces a Potent Suppression of Experimental Autoimmune Encephalomyelitis and Collagen-Induced Arthritis in Mice", Journal of Neuroimmunology, Elsevier Science Publishers BV XX, 1994, Vol. 53, No. 2, pp. 203-207.
	20	ELGER ET AL., Sulfamates of Various Estrogens are Prodrugs with Increased Systemic and Reduced Hepatic Estrogenicity at Oral Application, J. Steroid Biochem. Molec. Biol., 1995, Vol. 55, No. 3 / 4, pp. 395-403.
	21	MURPHY ET AL., Endometrial Effects of Long-Term Low-Dose Administration of RU486, Fertility and Sterility, April 1995, Vol. 63, No. 4, pp. 761-766.
	22	REEL ET AL., Survey and Assessment of Mammalian Estrogen Biological Assays for Hazard Characterization, Fundamental and Applied Toxicology, 1996, Vol. 34, pp. 288-305.
	23	BERAL ET AL., Use of HRT and the Subsequent Risk of Cancer, Journal of Epidemiology and Biostatistics, 1999, Vol. 4, No. 3, pp. 191-215.
	24	TAVANI ET AL., The Adverse Effects of Hormone Replacement Therapy, Drugs & Aging, May 1999, Vol. 14, No. 5, pp. 347-357.
	25	PIKE ET AL., Progestins and Menopause: Epidemiological Studies of Risks of Endometrial and Breast Cancer, Steroids, 2000, Vol. 65, pp. 359-664.
	26	AVVAKUMOV ET AL., Steroid-binding Specificity of Human Sex Hormon-binding Globulin Is Influenced by Occupancy of a Zinc-binding Site, The Journal of Biological Chemistry, August 25, 2000, Vol. 275, No. 34, pp. 25920-25925.

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O.Box 1450, Alexandria, VA 22313-1450.

{W0202225.1}